

NOTICE OF OFFICE OF MANAGEMENT AND BUDGET ACTION

AC65-2 059
PDR ~~659~~

TO: BRENDA JO. SHELTON (7714-MN83)
NRC CLEARANCE OFFICER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555
Nuclear Regulatory Commission

ACTION DATE

06/26/92

ON 12/24/91, YOU REQUESTED APPROVAL OF THE FOLLOWING INFORMATION COLLECTION:
TITLE: MEDICAL USE OF BYPRODUCT MATERIAL - 10 CFR PART 35
AGENCY FORM NOS.:

IN ACCORDANCE WITH THE PAPERWORK REDUCTION ACT, WE HAVE TAKEN THE FOLLOWING ACTION ON THIS INFORMATION COLLECTION:

NOT APPROVED. SEE "REMARKS" BELOW.

EFFECT ON BURDEN:	RESPONSES	REPORTING HOURS
PREVIOUS STATUS	8,422,955	303,782
NEW STATUS	8,422,955	303,782
DIFFERENCE	0	0

REMARKS:

See attached letter.

OMB NO. 3150-0010

ABSTRACT:

RADIATION SAFETY, NUCLEAR MEDICINE, RADIATION THERAPY, BYPRODUCT MATERIAL

THIS AMENDMENT REQUIRES LICENSEES TO ESTABLISH AND MAINTAIN A WRITTEN QUALITY MANAGEMENT (QM) PROGRAM AND TO SUBMIT TO NRC A COPY OF THE PROGRAM AND A CERTIFICATION THAT IT HAS BEEN IMPLEMENTED. THE AMENDMENT ALSO MODIFIES THE NOTIFICATION, REPORTING, AND RECORDKEEPING REQUIREMENTS RELATED TO THE QM PROGRAM AND MISADMINISTRATIONS.

ALLOWANCE LETTER: NO

FUNCTION:

ON PLAN: NO

EXCEED BUDGET: NO

NO. OF FORMS: 1

USE: PUBLIC

RESPONDENTS: 2,400

RESPONSES: 8,422,955

3504(H): NPRM

REQUEST: REVISION

HOURS: 303,782

AFFECTED PUBLIC: NON-PROFIT INST

SMALL BUSINESS: YES ACTIVITY TYPE:

PURPOSE: REG/COMP

FREQUENCY: OCCAS & OTHER

COLLECTION METHOD: RKP RQT

RETENTION: 5 YRS COLLECTION AGENT: RCDKPNG RQT

CONFIDENTIALITY: NO

COMPULSORY STATUS: MANDATORY

FEDERAL COST: \$1,120

PUBLIC COST:

REVIEWER: Ron Minsk

ACTION !AUTHORIZING OFFICIAL !TITLE: DEPUTY ADMINISTRATOR!DATE
APPROVED BY: !/S/JAMES B. MACRAE FOR !OFFICE OF INFORMATION !06/26/92
 ! !AND REGULATORY AFFAIRS !



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

August 14, 1992

AC 65-2 060
PDR

James B. MacRae, Jr.
Acting Administrator and
Deputy Administrator
Office of Information and
Regulatory Affairs
Office of Management and Budget
Washington, D.C. 20503

Dear Mr. MacRae:

This is in response to your letter of June 26, 1992 in which OMB disapproved the information collection request (ICR) associated with the final amendment promulgated by the Nuclear Regulatory Commission (Commission) to 10 CFR Parts 2 and 35, entitled, "Quality Management Program and Misadministration." OMB concluded that this information collection request is not necessary for the proper performance of the functions of the agency and that the information will not have practical utility for the agency. This letter also addresses your partial disapproval of the ICR associated with amendments to the fitness for duty rule in 10 CFR Part 26, as reflected in your letters of May 26, 1992 and July 20, 1992.

The Commission fully supports the objectives of the Paperwork Reduction Act and strives to ensure that the private sector is requested to maintain or provide only such information as is needed to carry out regulatory responsibilities. In this vein, upon reconsideration, the Commission does not disagree with your conclusions regarding information collection requirements in our fitness for duty rule. The Commission will issue conforming changes to account for and accommodate your comments and partial disapproval of the ICR in those regulations in the near future.

On the other hand, for reasons specified below, pursuant to 44 U.S.C. 3507(c), the Nuclear Regulatory Commission has decided to override the OMB determination and requests that your office promptly assign a control number to the information collection request associated with the Quality Management and Misadministration Rule for a period of 3 years.

In its implementing regulations OMB specifies (5 CFR 1320.11, 1320.4(b) and (c)) that in approving an information collection request it evaluates whether (1) the agency has chosen the least burdensome means to obtain the information, (2) the information sought is available to the agency through

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August 14, 1992

some other means, and (3) the information sought has practical utility. Practical utility is defined (5 CFR 1320.7(o)) only as usefulness to the agency, taking into account the information's accuracy, adequacy, and reliability, and the agency's ability to process the information in a timely fashion.

Your disapproval of the ICR does not indicate that the information collection requirements are an unnecessarily burdensome way to obtain information about misadministrations and medical quality management programs, or that the information is available through some other means. Your disapproval relies on the third evaluation criterion described above and makes a finding of no practical utility. But, contrary to 5 CFR 1320.7(o), you do not discount the accuracy, reliability or adequacy of the information sought, or challenge the Commission's ability to process the information in a timely fashion. Your disapproval indicates that you have concluded that there is no need for the Commission's final rule and regulatory program to reduce injuries from misadministration and that, therefore, any paperwork burden that the rule would impose is unreasonable.

The Commission -- which is the agency charged with substantive responsibility for making such judgments -- continues to believe that its requirement for written quality management programs and misadministration reports, if complied with, has a reasonable likelihood of decreasing misadministrations (e.g. wrong dose or wrong patient) with a small incremental cost to licensees. Without the reporting and recordkeeping requirements, it would not be possible to implement and enforce these regulations effectively.

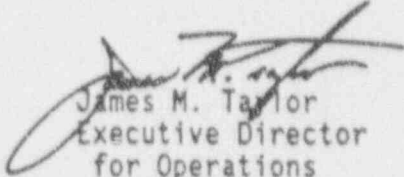
The Commission will continue to monitor implementation and inspection under the rule to assure that it provides the Commission with necessary information without imposing undue burden on the private sector. If the Commission finds the rule, in whole or in part, to be overly burdensome or ineffective, it will consider modifying or deleting portions of the rule. Further, the NRC will hold a public workshop with the medical community and other interested parties, to assure that there is mutual understanding as to the intent of the rule, especially its information collection requirements, and to discuss effective implementation. In particular, we will discuss the extent to which we can use the industry's self-auditing guidelines. Following the workshop, the Commission will develop additional guidance on compliance with the rule, written in clear language appropriate to the medical community.

August 14, 1992

Certification of the Override

The Commission certifies that, by unanimous vote¹, it has overridden the Office of Management and Budget's disapproval of the information collection request associated with the final amendment to 10 CFR Parts 2 and 35 entitled "Quality Management Program and Misadministration."

Sincerely,


James M. Taylor
Executive Director
for Operations

¹ At the August 12, 1992 Commission meeting the formal vote was 3-0 with Commissioners Rogers and Curtiss not present. Commissioners Rogers and Curtiss both indicated that they agreed with the majority and would also have voted formally to override if they could have been present at the meeting.

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AC 65-2
PDR ~~643~~



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

August 17, 1992

enclose the next 6 pages
and all info this
AND

The Honorable Bob Graham, Chairman
Subcommittee on Nuclear Regulation
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

This is to inform you that the Commission, by unanimous vote, has overridden the Office of Management and Budget's (OMB) disapproval of the information collection request associated with the final amendment to 10 CFR Parts 2 and 35 entitled "Quality Management Program and Misadministrations." A certification of the Commission's override has been forwarded to OMB in a letter dated August 14, 1992. A copy of the letter is enclosed.

In a letter dated June 26, 1992, OMB stated that it disapproved the information collection request because, in its view, the information collection is not necessary for the proper performance of the functions of the Agency and that the information collection will not have practical utility for the Agency.

The Commission fully supports the objectives of the Paperwork Reduction Act and strives to ensure that the private sector is requested to maintain or provide only such information as is needed to carry out regulatory responsibilities. However, the Commission continues to believe that its requirements for written quality management programs and misadministration reports, if complied with, has a reasonable likelihood of decreasing misadministrations (e.g., wrong dose or wrong patient) with a small incremental cost to licensees. Without the reporting and recordkeeping requirements, it would not be possible to implement and enforce these regulations effectively.

The Commission will continue to monitor implementation and inspection under the rule. If the Commission finds the rule, in whole or in part, to be overly burdensome or ineffective, it will consider modifying or deleting portions of the rule. Further, the NRC will hold a public workshop with the medical community and other interested parties, to assure that there is mutual understanding as to the intent of the rule, especially its information collection requirements, and to discuss effective implementation. Following the workshop, the Commission will develop additional guidance on compliance with the rule, written in clear language appropriate to the medical community.

In its letter to OMB dated August 14, 1992, the Commission also addressed OMB's partial disapproval of the information collection request associated with amendments to the fitness for duty rule in 10 CFR Part 26. Upon reconsideration, the Commission does not disagree with OMB's conclusions and will issue conforming changes to account for and accommodate OMB's comments

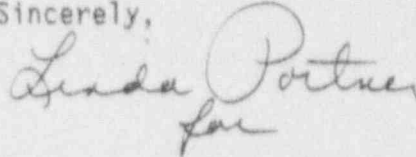
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The Honorable Bob Graham

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and partial disapproval of the information collection requirements in those regulations in the near future.

Sincerely,

A handwritten signature in cursive script, appearing to read "Linda Portner".

Dennis K. Rathbun, Director
Office of Congressional Affairs

cc: Senator Alan K. Simpson

Enclosure:

Ltr 8/14/92 Taylor, NRC to MacRae, OMB



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

August 17, 1992

AC 65-2
PDR

The Honorable Philip R. Sharp, Chairman
Subcommittee on Energy and Power
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

This is to inform you that the Commission, by unanimous vote, has overridden the Office of Management and Budget's (OMB) disapproval of the information collection request associated with the final amendment to 10 CFR Parts 2 and 35 entitled "Quality Management Program and Misadministrations." A certification of the Commission's override has been forwarded to OMB in a letter dated August 14, 1992. A copy of the letter is enclosed.

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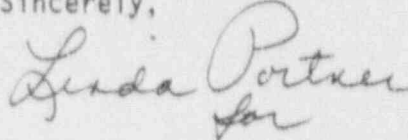
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The Honorable Philip R. Sharp

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and partial disapproval of the information collection requirements in those regulations in the near future.

Sincerely,

A handwritten signature in cursive script, appearing to read "Linda Portner", with a small flourish underneath.

Dennis K. Rathbun, Director
Office of Congressional Affairs

cc: Representative Carlos J. Moorhead

Enclosure:

Ltr 8/14/92 Taylor, NRC to MacRae, OMB



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

August 17, 1992

AC65-2
PDR

The Honorable Peter H. Kostmayer, Chairman
Subcommittee on Energy and the Environment
Committee on Interior and Insular Affairs
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

This is to inform you that the Commission, by unanimous vote, has overridden the Office of Management and Budget's (OMB) disapproval of the information collection request associated with the final amendment to 10 CFR Parts 2 and 35 entitled "Quality Management Program and Misadministrations." A certification of the Commission's override has been forwarded to OMB in a letter dated August 14, 1992. A copy of the letter is enclosed.

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The Honorable Peter H. Kostmayer

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and partial disapproval of the information collection requirements in those regulations in the near future.

Sincerely,

Linda Portner
for

Dennis K. Rathbun, Director
Office of Congressional Affairs

cc: Representative John J. Rhodes

Enclosure:

Ltr 8/14/92 Taylor, NRC to MacRae, OMB